DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
New Orleans District

4298 Elysian Fields Avenue
New Orleans, LA 70122
(504) 589-6341

November 4, 1996

WARNING LETTER NO. 13-7

CERTIFIED MAIL
RETURN RECEIPT REQUEST

Leonard J. Cheramie
Owner
Reds Seafood, Inc.
237 East 93rd Road
Cut Off, LA 70345

Dear Mr. Cheramie:

During an inspection of your crabmeat processing facility, located at 237 E. 93rd Road, Cut Off, LA, on 10/15-17/96, our investigator documented numerous objectionable insanitary conditions. This causes your finished product, picked crabmeat, to be adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug and Cosmetic Act (FD&C Act). Additionally, analysis of a sample consisting of all lump crabmeat collected from your production of 10/16/96, revealed the product to contain E. coli in 1 of 6 subsamples examined at a level of 9.1 MPN/g. This causes your product to be adulterated within the meaning of Section 402(a)(3) of the FD&C Act.

Objectionable conditions noted included: (1) employee routinely handling baskets and burlap sacks with live crabs then backing cooked crabs without washing and sanitizing hands; (2) baskets of cooked crabs placed directly upon the backing room floor; (3) a live cat in the backing room during operations; (4) baskets used for cooked crabs stored on the backing room floor, and the deck area outside; on one occasion, a cat rubbed against these baskets; (5) dirty encrusted baskets used to hold cooked crabs were also contaminated on their bottoms with floor splash, these basket bottoms were then placed on backing table when the cooked crabs were dumped; (6) a nylon net that routinely hung on the wall was used to transfer crabs from the boiler into baskets for transport into the backing room; (7) baskets of backed crabs stored in contact with the dirt encrusted walls; (8) condensate from the cooler unit dripping onto baskets of cooked crabs; (9) numerous improper employee practices in the backing room, including employees handling unsanitized dirty surfaces (trash cans, entering the plant from outside, backing room hose) and then handling cooked product; (10) backing room table pitted and contained encrusted residues from previous operations; (11) live flies outside and inside

the plant; (12) structural defects allowing for vermin entry; and, (13) numerous improper employee practices in the picking operation allowing for contamination of the finished produc with filth from dirty street clothing, inadequate picking equipment, and used paper towels.

The above identification of violations is not intended to be an all-inclusive list of deficiencies a your facility. It is your responsibility to assure adherence with each requirement of the Good Manufacturing Practice Regulations.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice. This may include seizure and/or injunction.

You should notify this office in writing, within 15 working days of receipt of this letter, of the steps taken to correct the noted violations, including an explanation of each step taken to preven the recurrence of similar violations. If corrective action cannot be completed within 15 working days, state the reason for this delay and the time within which the corrections will be completed

Your response should be directed to Richard D. Debo, Compliance Officer, U.S. Food and Drug Administration, 4298 Elysian Fields Avenue, New Orleans, Louisiana, 70122, telephone numbe (504) 589-7166. Should you have any questions concerning the contents of this letter, or if you desire a meeting with the agency staff, do not hesitate to contact Mr. Debo.

Sincerely,

James E. Gamet
District Director
New Orleans District Office

Enclosure: FDA-483
21 CFR, Part 110

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